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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MACLACHLAN & DONALDSON
47 Merrion Square
Dublin 2
IRLANDE

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)* 16.11.2001

Applicant's or agent's file reference
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**IMPORTANT NOTIFICATION**

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IE00/00092 | 28/07/2000 | 30/07/1999 |

Applicant
GAYA LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| ---- | | |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IE00/00092 | 28/07/2000 | 30/07/1999 |

International Patent Classification (IPC) or national classification and IPC
A61B17/34

Applicant
GAYA LIMITED et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 14 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 22/12/2000 | 16.11.2001 |

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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00092

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
**Description, pages:**

| | | |
|---|---|---|
| 1-21 | as originally filed | |

**Claims, No.:**

| | | |
|---|---|---|
| 1-21,27-33,34 (part), 39-63 | as originally filed | |
| 22-26,34 (part), 35-38 | with telefax of | 10/08/2001 |

**Drawings, sheets:**

| | | |
|---|---|---|
| 1/13-13/13 | as originally filed | |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*
**see separate sheet**

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 26-35,42, 43-63 (incorrectly numbered 43-62).

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 26-35,42-63 are so unclear that no meaningful opinion could be formed (*specify*):
**see separate sheet**

☒ the claims, or said claims Nos. 43-63 are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 42.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:
   **see separate sheet**

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1-5,8,11-13,15-25,36-41 |
| | No: | Claims | 6,7,9,10,14 |
| Inventive step (IS) | Yes: | Claims | 1-5, 20-25,38-41 |
| | No: | Claims | 6-19,36,37 |
| Industrial applicability (IA) | Yes: | Claims | 1-25,36-41 |
| | No: | Claims | |

2. Citations and explanations
   **see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
**see separate sheet**

## I. Basis of the opinion

The following amendment filed with the letter dated 10.08.01 introduces subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amended claim 26 (originally independent claim, at present made dependent on claim 14) defines an access port device comprising two outer annular sealing devices (one defined in claim 14, the second introduced in claim 26) and two inner annular sealing devices (one defined in claim 14, the second introduced in claim 26). Such a combination of features is not disclosed and nor derivable from the original disclosure.

According to Rule 70.2(c) PCT, the corresponding amendment was not considered for the establishment of the present report, that is to say the **original independent claim 26 and its dependent claims 27-35** were taken into account (see item III).

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

**III.1.** No meaningful opinion can be formed with regard to novelty and inventive step of **claim 42** (Article 34(4)(b) PCT) because the matter for which protection is sought is not clearly defined (Article 6 PCT).
The claim relies only on references to the description and drawings which do not define any clear structural limitations. According to Rule 6.2(a)PCT (see also the PCT Guidelines, III-4.10), claims should not contain such references except where absolutely necessary, which is not the case here (see the previous claims).
It is also to be noted that no international search report has been established for the said claim under Article 17 PCT

**III.2.** No meaningful opinion can be formed with regard to novelty and inventive step of **claims 26-35** because of a lack of clarity (Article 6 PCT) as explained below.
Considering the fourth invention of the application, this latter lacks conciseness and clarity in that the subject-matter of claims 26-35 appears to be already defined in claims 19-25, dependent on the independent claim 14.

**III.3.** No meaningful opinion can be formed with regard to novelty and inventive step of **claims 43-63** (incorrectly numbered 43-62, see the comments of item VII.5) (Article 34(4)(b) PCT) because of lacks of clarity (Article 6 PCT) as explained below.

In the **independent claim 43**, it is not clear what should be defined by "mounting means for locating and securing the device in position on a patient". Considering the embodiments of the description, which comprise a "retractor" (feature also defined in this independent claim), that is to say the embodiments represented in figures 10-22 and described from page 17, last paragraph, to page 21, first paragraph, it is to be mentioned that they do not provide elements which could help the skilled reader to understand what is covered by the functional definition cited above, contrary to the requirements of Article 5 PCT.
Furthermore, in the last line of this claim it is referred to "the sleeve" whereas such a feature is not previously defined as part of the invention.
Consequently, independent claim 43 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined.

With regard to the dependent claims, the following is to be mentioned:

- **Dependent claims 46 and 48** do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of functional statements and desired result rather than in structural terms (see the PCT Guidelines, III-4.7 and 4.8a). The intended structural limitations to the device itself are not clear from these claims.

- **Dependent claims 46 and 62** (incorrectly numbered 61) lack clarity in that there is no antecedent basis for "the sleeve".

- **Dependent claims 47, 49 and 50** lack clarity in that it is not clear to which one of the two distinct rings defined in claim 45 ("a proximal and a distal ring") it is referred by the expression "the ring".

In view of the further prosecution of the application in the regional phase, the following remark appear appropriate. Most of the features of the fourth invention as defined in the description appear to be anticipated by the prior art surgical devices disclosed in documents WO-A-98/35614 (=D2) and US-A-5 906 577(=D3) (see the whole documents).

## IV. Lack of unity of invention

As the International Searching Authority pointed out, the application consists of four different groups of inventions which are not so linked as to form a single general inventive concept in the sense of Rule 13.1 PCT.
The separate inventions (groups of invention) are:

1. Claims 1-5 : Access port device with first and second sleeve, securing device and third sleeve including annular elastic band;

2. Claims 6-13 : Access port device with first and second sleeve, securing device and second sleeve retraction prevention device;

3. Claims 14-42 : Access port device with sleeve, annular inner and outer sealing device;

4. Claims 43-62 (incorrectly numbered 63) : Access port device with sleeve, mounting means, sealing means and retractor for sleeve contact limitation

An access port device comprising a first and second sleeve and a securing device is known from prior art document US-A-5 899 208 (cited in the description of the present application).

1. Claim 1 describes an access port device comprising a third sleeve including an annular elastic band therefore defining a special technical feature in comparison with the prior art (US-A-5899208) for the first invention.

2. Claim 6 describes an access port device comprising a second sleeve retraction prevention means therefore defining a special technical feature in comparison with the prior art for the second invention.

3. Claim 14 describes an access port device comprising an inner and outer annular sealing device therefore defining a special technical feature in comparison with the prior art for the third invention.

4. Claim 43 describes a surgical instrument defining a sleeve access port comprising a retractor therefore defining a special technical feature in comparison with the prior art for the fourth invention.

The respective technical features defined for each invention are neither the same nor corresponding as they also solve different problems, namely:

1. "to sealingly engage a surgeon's arm" (claim 1) and hence preventing air from leaking between surgeon's arm and access device;

2. preventing unwanted retraction of the sleeve during surgery;

3. sealingly engage the incision edges and hence preventing air from leaking between incision edges and access device;

4. "limiting the contact between the sleeve and the incision when in use" (claim 43).

Therefore the requirement of unity of invention (Rule 13.1 PCT) is not fulfilled. Since the applicant paid additional examination fees, the International Preliminary Examining Authority proceeds to the substantive examination of all the claimed inventions.

## V. Reasoned statement under Article 35(2) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO-A-95/22289
D2: WO-A-98/35614
D3: US-A-5 906 577

### V.1. First invention (claims 1-5)

#### V.1.1. Independent claim 1

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (see figures 13-16; the references in parentheses applying to this document) an access port device for use in surgery, comprising:

- a first sleeve (42) of flexible material including a proximal end and a distal end;

- a securing device (44) attached to said distal end of said first sleeve to secure the access port device externally to a patient;

- a second sleeve (41) of flexible material attached to the proximal end of said first sleeve, said second sleeve including an entry opening adjacent said proximal end of said first sleeve and an exit opening positioned a spaced distance

from said entry opening (see second figure 15);

- an inflatable chamber (46, 47",48") formed between said first and said second sleeves;

- a third sleeve of flexible material attached to at least one of said first sleeve and said second sleeve (see figure 13, second figure 15, elements 103, 50, and page 22, lines 4- 32).

The subject-matter of claim 1 therefore differs from this known access port device in that the third sleeve further includes an annular elastic band positioned between said entry and said exit openings of said second sleeve.
The problem to be solved by the present invention may therefore be regarded as to improve the sealing action, by providing a tight sealing around the surgeon's arm extending through the third sleeve.
None of the other available prior art discloses an access port comprising three sleeves as defined in claim 1 and there is no indication in this prior art that would prompt the skilled person from the closest prior art to the invention. The solution to the problem of gas leakage proposed in independent claim 1 of the present application is, therefore, considered as involving an inventive step (Article 33(3) PCT).

**V.1.2.** Dependent claims 2-5

**Claims 2-5** fulfil also the requirements of Articles 33(2) and (3) PCT as being dependent from the above-mentioned independent claim.

**V.2.** Second invention (claims 6-13)

**V.2.1.** Independent claim 6

The document D1 is regarded as being the closest prior art to the subject-matter of claim 6, and discloses (see figure 14, page 17, lines 3-10 and page 20, line 24- page 21, line 21; the references in parentheses apply to this document) an access port device for use in surgery, comprising:

- a first sleeve (42) of flexible material including a proximal end and a distal end;

- a securing device (44) attached to said distal end of said first sleeve to secure the access port externally to a patient;

- a second sleeve (41) of flexible material attached to the proximal end of said first sleeve, said second sleeve including an entry opening adjacent said proximal end of said first sleeve and an exit opening positioned a spaced distance from said entry opening for insertion into an incision formed in a patient's body;

- an inflatable chamber (46, 47", 48") formed between said first and said second sleeves;

- an elongated exit opening seal (102) mounted on said second sleeve at said exit opening, said exit opening seal positioned along an exit opening seal plane extending through said entry opening and said exit opening of said second sleeve;

- a second sleeve retraction prevention means for preventing inadvertent retraction of said second sleeve from the incision (see page 20, line 24-page 21, line 16), said second sleeve retraction prevention means including at least one transverse wing (56) extending transverse to said exit opening seal plane.

Thus, the subject-matter of **independent claim 6** is not novel in the sense of Article 33(2) PCT with respect to document D1:

**V.2.2.** Dependent claims 7-13

**Dependent claims 7, 9 and 10** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT), document D1 showing:

- one wing (56) on each side of said exit opening (see figures 14), as claimed in claim 7;

- a wing integrally formed on said exit opening seal (see figures 14 and page 20, last paragraph), as claimed in claim 9;

- a pair of opposed bands (55) as defined in claim 10 (see page 21, lines 2-16).

**Dependent claims 8 and 11-13** merely define slight constructional changes (namely the introduction of additional wings) in the access port device of claim 6, which come within the scope of the customary practice followed by persons skilled

in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, these claims do not involve an inventive step and do not satisfy the criterion set forth in Article 33(3) PCT.

**V.3.** Third invention (claims 14-41)

**V.3.1.** Independent claim 14

The document D3 is regarded as being the closest prior art to the subject-matter of claim 14, and discloses (see figures 5, 6 and column 9, lines 7-42; the references in parentheses apply to this document) an access port device for use in surgery, comprising:

- a sleeve (sleeve of the retractor 200) of flexible material including a proximal end and a distal end, and forming an access opening positionable in an incision in a patient's body;
- an outer annular sealing device (the top ring of the represented retractor 200) to secure the access port device externally to a patient;
- an inner annular sealing device (the bottom ring of the represented retractor 200) attached to said distal end of said sleeve to secure the access port device internally to the patient;
- an access component (202 of figure 5 or alternative of figure 6A) removable connected to said outer annular sealing device, said access component including a flexible ring (204 in figure 5 or 70 in figure 6A) removable engaging said outer annular sealing device.

Thus, the subject-matter of **independent claim 14** is not novel in the sense of Article 33(2) PCT with respect to document D3.

**V.3.2.** Dependent claims 15-25 and 36-41 (for claims 26-35, see the comments of Sections I and III)

**Dependent claims 15-19, 36 and 37** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being the following:

- an access component including a sleeved glove or an access sleeve with an integral glove, as defined in claims 15 and 16 respectively, have already employed in similar devices (see, for example, document D2, figure 2). The skilled person would regard it as a normal option to include such features in the device disclosed in D3 (see also figures 10 and 11);

- Claims 17 and 18 merely define slight constructional changes in the device of D3 (see column 9, lines 18-20) which come within the scope of the customary practice followed by a person skilled in the art;

- Document D3 shows a device comprising an access component including an inflatable chamber as defined in claim 19 (see the embodiment of figure 4);

- A non adhesive outer annular sealing and a removable access component are known per se from document D3 (see figure 5). The fact that the access component is extendable into the access opening is an advantageous configuration already known in similar devices (see the comments relating to the glove-shaped sleeve above). Thus, the subject-matter of claims 36 and 37 does not involve an inventive step.

The combination of the features of **dependent claims 20 or 38** is neither known from, nor rendered obvious by, the available prior art.

**Claims 21-25 and 39-41** are dependent on claims 20 and 38 respectively and as such also meet the requirements of the PCT with respect to novelty and inventive step (Article 33(2) and (3) PCT).

## VII. Certain defects in the international application

**VII.1.** Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D2 and D3 are not mentioned in the description, nor are these documents identified therein.

**VII.2.** Contrary to the requirements of Rule 6.2(b) PCT, the features of the claims are not provided with reference signs placed in parentheses (see also the PCT Guidelines III-4.11).

**VII.3.** The independent claims are not drafted in the two-part form as required by Rule

6.3(b) PCT.

**VII.4.** In dependent claim 12, the number "5" should have been deleted (page 24, line 13).

**VII.5.** The application comprises two claims numbered 58. The claims numbered 58(second)-62 by mistake should have been renumbered 59-63 and the dependency of these claims should have been modified accordingly.

**VII.6.** The identification of a patent with its application number is not possible for the public who has no access to the software referencing patent families. Thus, it should have been more appropriate to identify the prior art document cited on page 2, line 6, with its publication number, namely WO-A-95/07056.

**VII.7.** Minor defects:

- The figures do not show the item "4" stated in the description on page 11, line 20, page 14, line 11 and page 15, second paragraph (Rule 11.13(l)PCT);
- Page 18, line 16, reference sign "6" should have been corrected into "2006";
- Page 18, line 20, reference sign "2063" should have been corrected into "2062";
- Page 18, line 27, reference sign "2000" should have been corrected into "2002";
- The figures do not show the item "1202" stated in the description on page 20, lines 9 and 11(Rule 11.13(l)PCT).

## VIII. Certain observations on the international application

**VIII.1.** The term "substantial", used in combination with the term "portion" in **dependent claim 3**, is vague and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT). Such a term should have been avoided (see also the PCT Guidelines, III-4.5a).

**VIII.2.** The subject-matter of **dependent claim 37** appears to be already contained in the independent claim 14 (see page 25, lines 1-3). Therefore, the present application does not meet the requirement of conciseness (Article 6 PCT).

22. An access port device as claimed in claim 20 or claim 21, further including a gas chamber positioned adjacent said inner annular biasing surface to collect gas leaking between said sleeve and the patient's body.

23. An access port device as claimed in any of claims 20 to 22, wherein said flexible annular extension is generally flat.

24. An access port device as claimed in claim 22, wherein said outer annular sealing device includes an upper annular overhang positioned opposite and spaced from said flexible annular extension, said gas chamber being positioned between said upper annular overhang and said flexible annular extension.

25. An access port device as claimed in claim 20, said outer annular sealing device further including an outer biasing surface facing said inflatable chamber to cause gas pressure in said inflatable chamber to apply a gas pressure sealing force against said outer biasing surface to bias said outer annular sealing device into abutment with the patient's outer surface.

26. An access port device as claimed in claim 14 in which the sleeve of flexible material comprises a first sleeve, including

a leakage minimizing means for minimizing gas leakage from between said first sleeve and the patient's body, said leakage minimizing means including an outer annular sealing device attached to said proximal end of said first sleeve, an inner annular sealing device attached to said distal end of said first sleeve for abutting and sealingly engaging an inner surface of a body cavity of the patient, and a sealing force applying means for causing leakage gas between said first sleeve and the patient's body to apply a sealing force against said outer annular sealing device to bias said outer annular sealing device toward the patient.

cause a sealing force to bias said outer annular sealing device into sealing engagement with the patient's skin.

35. An access port device as claimed in claim 33, wherein sealing force applying means further includes an outer biasing surface formed on said overhang and adapted to receive gas pressure biasing forces tending to bias said overhang into abutment with the patient's outer surface.

36. An access port device as claimed in claim 14 in which the outer annular sealing device is a non adhesive device and is adapted to create a non adhesive, substantially gas-tight seal adjacent the patient's body to prevent gas flow from the patient's body and the access component is sealingly mounted on said outer annular sealing device and extendable into said access opening.

37. An access port device as claimed in claim 36, wherein said access component is removably mounted on said outer annular sealing device.

38. The access port device of claim 37, wherein said non adhesive outer annular sealing device includes a flexible annular extension extending radially inwardly and an inner biasing surface formed on said flexible annular extension and facing outwardly away from the patient's body.